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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/445,963 | 12/16/1999 | TOHRU TANAKA | Q57226 | 1604 |

7590 02/06/2004

SUGHRUE MION ZINN MACPEAK & SEAS
2100 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20037

EXAMINER

YU, MISOOK

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 02/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/445,963

Applicant(s)

TANAKA ET AL.

Examiner

MISOOK YU, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003 and 04 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 20, 2003 and September 22, 2003 have been entered.

Claims 12 and 13 are new, and claims 10-13 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Response to Arguments

Claim Rejections - 35 USC § 103

Claims 10 and 11 **remain rejected** and new claims 12 and 13 are also under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (1994, ACS Symp. Ser., pp.291-302) in view of Jichlinski, et al (1996, Pro. SPIE-Int. Soc. Opt. Eng. pp.340-347), Kajiwara (1990, JP 02111747), and Jaffe, et al (1990, Biochemistry, pp.8345-50).

The instant claims are drawn to method of cancer detection and treatment by administering carbon or nitrogen isotope labeled 5-ALA to patient, followed by detecting cancer using NMR, then treating said patient.

Since applicant did not argue in the remarks section of the amendment filed on 10/20/2003, and the Office will address applicant's arguments filed on 09/22/2003.

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Point 1

Applicant argues that Jaffe and Kajiwara, isotope-labeled 5-ALA is administered to a living body to undergo biochemical reaction in the living body. Synthesized porphobilinogen (PBG) is then separated by extraction, and the position of the isotope is analyzed by NMR to clarify the function of ALA dehydratase which produces PBG. Therefore, in Jaffe and Kajiwara, NMR is not used for the detection of 5-ALA in the living body, the analysis of the position of the isotope is carried out for PBG purified in vitro, so in vivo experiments are not carried out in Jaffe and Kajiwara, Kajiwara only discloses that PBG is useful as a therapeutic for lead poisoning, but does not disclose diagnosis of malignant tumors, Kajiwara also does not teach the administration of 5-ALA into the living body.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Point 2

In response to the last full paragraph on page 2 of the Office's action mailed on 5/20/2003,

Applicant further argues that even if the references were to be combined, one of ordinary skill in the art would not be reasonably motivated to expect a reasonable chance of success that the amount of the isotope label could be measured in a living body and that the result could be applied to medical techniques at tissue in the present claims. This argument is not persuasive, either because the specification at 25-26 and the NMR data at Fig. 1, the amount of the isotope label is not measured in a living body, but measured outside of a living body, using the same NMR techniques taught by Jaffe et al.

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Applicant appears to argue that the instant specification does not have to teach the technical details of the instant invention by saying that one in ordinary skill would know how much radio labeled 5-ALA is necessary in vivo MRI or NMR spectroscopy. This argument is not persuasive because this argument appears to contradict applicant's earlier argument at the paragraph bridging pages 5 and 6 of the amendment filed on 2/26/2003; applicant argued that the instant invention is not obvious because there is no expectation of success based on the prior art disclosure.

Point 3

Applicant appears to seek advice on allowable subject. However, the Office is not able to state what is allowable at this point because applicant has not overcome the rejection of record. It would be helpful if applicant clearly states what is the inventor's discovery and/or improvement on the record, and why said discovery and/or improvement is not obvious given what is known in the art and what is disclosed in the instant application.

Point 4

Applicant appears to argue that the art of record cited for making obviousness rejection for detection part of the invention deals with metabolic studies using radio labeled ALA, therefore the researchers in metabolic studies would not be motivated to use the product in medical imaging. This argument is fully considered but found unpersuasive because one in ordinary skill does not necessarily has to be the same person or in the same field. One in medical imaging field would be motivated by

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reading metabolic studies. One in ordinary skill would encompass both i.e. metabolic studies and medical imaging researchers.

For the argument using Kajiwara, this argument is already addressed in Point 1 above i.e. one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne C Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Misook Yu

January 30, 2004

A handwritten signature in black ink, appearing to be 'L. Helms', written in a cursive style.

LARRY R. HELMS, PH.D
PRIMARY EXAMINER